REMARKS

I. PRELIMINARY REMARKS

Claims 1, 7, 8, 10, 12, 18, 19, 21, 23, 34-42 and 46 have been amended. Claims 5, 6, 16, 17, 29 32, 33 and 43-45 been canceled. No claims have been added. Claims 1-4, 7-15, 18-28, 30, 31, 34-42 and 46 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes that the claim numbering in the application, as filed, skipped number "35." Accordingly, ***claims 36-47 have been renumbered 35-46*** and the "Remarks" section of this amendment reflects this renumbering.

II. BRIEF DESCRIPTION OF AN EXEMPLARY EMBODIMENT

The present inventions, as defined by the claims, are directed generally to forming lesions in body tissue and determining whether or not therapeutic lesions have been formed. Referring to Figure 14, an exemplary suction device 404 includes a main body 407 with a plurality of suction ports 410 and slot 420. The slot 420 may be used as a connector to secure a portion of a surgical probe 100', with a plurality of electrodes 110, to the suction device 404. The suction device 404 may, in turn, be used to fix the position of the surgical probe 100' during a lesion formation procedure.

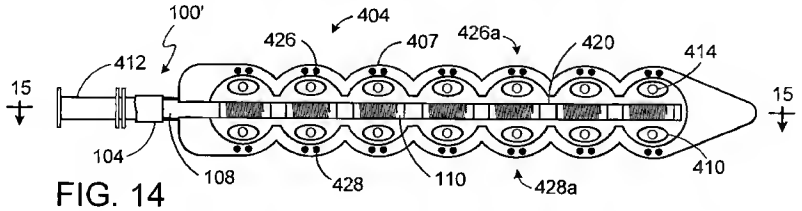

FIG. 14

The suction device 404 also includes stimulation electrodes 426 and sensing electrodes 428 on the main body 407. The slot 420 is between the stimulation electrodes 426 and the sensing electrodes 428 and, accordingly, the stimulation electrodes 426 and sensing electrodes 428 will be on opposite sides of the lesions

formed by the surgical probe 100'. The suction device 404 may be used to stimulate tissue on one side of the lesion, and sense tissue on the other side of the lesion, to determine whether or not a therapeutic lesion has been formed by the surgical probe 100'. [Specification at, for example, page 28, line 27 to page 30, line 28.]

III. PRIOR ART REJECTIONS

A. The Rejections

Claims 1-5, 7, 8, 10-16, 18, 19, 21-28, 30-32, 34-46 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,706,038 to Francishelli ("the Francishelli '038 patent"). Claims 6, 9, 17, 20, 29 and 33 have been rejected under 35 U.S.C. § 103 as being unpatentable over the Francishelli '038 patent. As claims 5, 6, 16, 17, 32, 33 and 43-45 have been canceled, it is respectfully submitted that the rejections thereof under 35 U.S.C. §§ 102 and 103 have been rendered moot. The rejections of the remaining claims under 35 U.S.C. §§ 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Francishelli '038 patent

The Francishelli '038 patent is directed to a two-part lesion formation apparatus. Referring to Figure 1, the apparatus includes an ablation device 20 with an electrode 22 that is placed on the front surface of the target tissue 60, and a pad-type sensor 24, with temperature sensing elements 34 on a support surface 44, that is placed on the back surface of the target tissue 60. [Note column 6, lines 6-10.] During a lesion formation procedure, energy is applied by the ablation device 20 to the front surface of the target tissue 60, and lesion transmurality is assessed based on the temperature on the back surface of the target tissue measured by the sensor 24. A return electrode 23 may be placed on the patient, incorporated into the ablation device 20, or incorporated into the sensor 24.

The Francishelli '038 patent discloses a number of alternative embodiments. For example, the ablation device 20 may include suction elements. [Column 10, lines 24-26.] An alternative temperature sensor 24, which includes suction ports 986, is illustrated in Figure 9. The Francishelli '038 patent also indicates that "electrodes used to stimulate or monitor the heart may or may not be incorporated into ablation device 20 and/or sensor 24." [Column 16, lines 23-26.]

Applicant notes here that the Office Action appears to have mixed and matched elements from various portions the Francishelli system. For example, the Office Action appears to have taken the position that the support surface 44 of the sensor 24 is somehow configured to secure the ablation device 20 to the sensor 24. [Office Action at page 3, lines 1-3.] Given the fact that ablation device 20 and sensor 24 are not even positioned on the same side of the target tissue 60 during use (Figure 1), this is clearly an unreasonable interpretation of the reference.

C. Discussion Concerning Claims 1-4, 7-15, 18-28, 30, 31 and 34-37

Independent claim 1, 12 and 23 call respective combinations that comprise, *inter alia*, "a main body," "a suction region associated with the main body," "a stimulation element on the main body," "a stimulation energy sensing element on the main body" and "***a connector, located between the stimulation element and the stimulation energy sensing element***, configured to secure at least a portion of the electrophysiology device to the main body adjacent to the suction region." The respective combinations defined by claims 2-4 and 7-11 include, *inter alia*, the elements recited in independent claim 1, the respective combinations defined by claims 13-15 and 18-22 include, *inter alia*, the elements recited in independent claim 12, and respective combinations defined by claims 24-28, 30, 31 and 34-37 include, *inter alia*, the elements recited in independent claim 23.

The Francishelli '038 patent fails to teach or suggest such combinations. For example, the Francishelli '038 patent discloses that the ablation device 20 can include suction elements as well as stimulation and sensing electrodes. Even assuming for the

sake of argument that the electrode 22 is an "electrophysiology device," and that the ablation device 20 includes a "connector" which secures the electrode 22 to the ablation device 20 adjacent to the suction elements, there is nothing in the Francishelli '038 patent that even remotely suggest placing the connector between the stimulation and sensing electrodes. The rejection under 35 U.S.C. § 102 should, therefore, be withdrawn.

In the context of the rejection under 35 U.S.C. § 103, the Office Action appears to have taken the position that it would have been obvious to arrange the Francishelli suction elements, stimulation electrodes, and sensing electrodes on opposite sides of the purported "connector." In support of the conclusion of obviousness, the Office Action appears to have asserted that (1) the Francishelli '038 patent discloses that the suction ports 986 may be arranged in a variety of ways, (2) the Francishelli '038 patent discloses "much flexibility toward ... [the] placements" of the stimulation and sensing electrodes, and (3) the disclosure of placement flexibility "implies" motivation to use "different placements to increase the number of applications for which the device could be used." There are a plethora of factual and legal errors associated with these assertions.

For example, with respect to assertion (1), the suction ports 986 are part of the sensor 24, not the ablation device 20.[1] Concerning the ablation device 20, the Francishelli '038 patent merely states that "[a]blation device 20 may comprise one or more suction elements" and does not discuss their location. [Column 10, lines 24-26.] Turning to assertion (2), the Francishelli '038 patent does not discuss the locations of the stimulation and sensing electrodes above and beyond the fact that they "may be incorporated into the ablation device 20 and/or sensor 24." [Column 16, lines 22-26.] Finally, applicant is unaware of any support for the "implied motivation/rearrange parts to increase applications" obviousness standard associated with assertion (3) and hereby requests that the next Office Action provide support therefor from the applicable case law and/or

[1] If, on the other hand, it is the Examiner's position that the sensor 24 corresponds to the claimed apparatus to which an electrophysiology device is secured, applicant hereby requests that the next Office Action specifically say so in order to clarify the issues in this application.

MPEP. The following passage from MPEP § 2144.04-III-C certainly "implies" that such support does not exist:

> The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. ***The prior art must provide a motivation or reason*** for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device.

[Citations omitted, emphasis added.] Finally, it is also worth reiterating here that the Francishelli system does not evaluate lesion transmurality through stimulation and sensing. Instead, the Francishelli system evaluates lesion transmurality as a function of the temperature measured on the back side of the target tissue 60 by the sensor 24, while energy is being applied, by the electrode 22, to the front side of the target tissue. [Figure 1.]

In view of the forgoing, applicant respectfully submits that the rejection under 35 U.S.C. § 103 should also be withdrawn.

D. Discussion Concerning Claims 38-42 and 46

Independent claim 38 calls for a combination of method steps including, *inter alia*, "forming a lesion in tissue," "transmitting stimulation energy to the tissue on one side of the lesion" and "monitoring tissue to sense a local excitation caused by the transmitted stimulation energy on the other side of the lesion." The respective combinations recited in claims 39-42 and 46 include, *inter alia*, the elements recited in independent claim 38.

The Francishelli '038 patent fails to teach or suggest such combinations. For example, although the Francishelli '038 patent indicates that "electrodes used to stimulate or monitor the heart may or may not be incorporated into ablation device 20 and/or sensor 24," the nothing in the Francishelli '038 patent even remotely suggest transmitting stimulation energy to tissue on one side of a lesion and monitoring tissue on the other side of the lesion to sense local excitation.

As the Francishelli '038 patent fails to teach or suggest each and every element of the combination recited in independent claim 38, applicant respectfully submits that

claims 38-42 and 46 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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Date

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